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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,088	12/08/2000	Herbert Herzog	12020-0003	4580

7590 03/11/2003

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/11/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/719,088

Applicant(s)

HERZOG, HERBERT

Examiner

J. Eric Angell

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-7, 10 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 is/are allowed.
- 6) ☒ Claim(s) 3-5, 10 and 26-33 is/are rejected.
- 7) ☐ Claim(s)    is/are objected to.
- 8) ☐ Claim(s)    are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on    is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on    is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No.   .
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>  </u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)             | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>  </u> | 6) <input type="checkbox"/> Other: <u>  </u>                                   |

### **DETAILED ACTION**

1. This Action is in response to the communication filed on 12/19/02, as Paper No. 13.

Claims 1, 2, 8, 9 and 11-14 have been canceled. Claims 3-7 and 10 have been amended. New claims 26-33 have been added. Claims 2-7, 10 and 26-33 are currently pending in the application and are addressed herein.

2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

3. It is noted that a species election was set forth in a previous Office and applicants elected the species of a nucleic acid of SEQ ID NO. 4 (which encodes SEQ ID NO. 2, human NPY-Y7). Therefore, claim 6 is withdrawn from consideration as it is drawn to a non-elected species (a nucleic acid encoding SEQ ID NO. 3, murine NPY-Y7). It is noted that the previous was in error for removing claim 4 from consideration because I was drawn to a nucleic acid sequence encoding SEQ ID NO. 2, and claim 4 will be examined in this non-final action.

### ***Claim Rejections - 35 USC § 112, second paragraph***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is drawn to an isolated polynucleotide molecule which encodes a human NPY-7 receptor having an amino acid sequence **corresponding to that shown in SEQ ID NO. 2.**

(Emphasis added). The phrase “an amino acid sequence corresponding to that shown in SEQ ID NO. 2” renders the claim indefinite because it is unclear how a sequence can “correspond” to another sequence. It is unclear if the claimed sequence comprises the exact sequence shown in SEQ ID NO. 2, or if the claimed sequence comprises any part (i.e. fragment) of the sequence shown in SEQ ID NO. 2. Amending the claim is required. An example of an acceptable claim is “An isolated polynucleotide which encodes the amino acid sequence set forth in SEQ ID NO. 2.”

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 3-5, 10 and 26-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. Claim 3 is drawn to an isolated polynucleotide encoding an NPY-Y7 receptor of human origin 408 amino acids in length. This claim encompasses any isolated polynucleotide encoding an NPY-Y7 receptor of human origin 408 amino acids in length—which would include

Art Unit: 1635

substitutions (as well as additions coupled with deletions) of SEQ ID NO. 2 and would also encompass any naturally occurring allelic variants of SEQ ID NO. 2 as long as the polypeptide was 408 amino acids in length. (Note: claims 10 and 26-33 depend on claim 3 and thus encompass all of the possible variants encompassed by claim 3)

9. Claim 4 is drawn to an isolated polynucleotide molecule which encodes a human NPY-7 receptor having an amino acid sequence corresponding to that shown in SEQ ID NO. 2. Therefore the claim encompasses any receptor having any fragment of SEQ ID NO. 2 (as mentioned above).

10. Claim 5 is drawn to an isolated polynucleotide encoding an NPY-Y7 receptor of murine origin 405 amino acids in length. Similar to the rejection of claim 3 above, this claim encompasses any isolated polynucleotide encoding an NPY-Y7 receptor of murine origin, as long as the polypeptide is 405 amino acids in length, regardless of substitutions and additions/deletions.

Therefore the claims encompass sequences for which there is insufficient written description provided in the specification.

The Written Description Guidelines for examination of patent applications indicates, “the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus.” (See MPEP 2100-164).

Art Unit: 1635

The instant claims encompass nucleic acids which are different from those disclosed in the specification, and include variants for which no written description is provided. This large genus is represented in the specification by only the named SEQ ID Nos (nucleic acid sequences of SEQ ID No. 4 and 5, which encode the sequences of SEQ ID Nos 2 and 3). Thus, applicant has express possession of only SEQ ID Nos: 2/4 and 3/5, in a genus which comprises hundreds of millions of different possibilities considering every possible substitution (and fragment in the case of claim 4) encompassed by the claims. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

Here, no function or no common structural elements or attributes of the sequences are disclosed. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided.

In the instant application, certain specific sequences are described, but no the structures which are critical to the function of the encoded receptors are not disclosed.

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acid sequences other than those expressly disclosed which represent functional portions, mutations or other polymorphisms. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Art Unit: 1635

11. Claims 3-5, 10 and 26-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, in view of the written description rejection set forth above.

As mentioned above, the claims encompass sequence for which there is no written description provided in the specification and for which include substitutions, fragments, etc. of disclosed sequences. Without a clear indication of the sequence encompassed by the claims one of skill in the art would not know how to make or use the claimed invention without performing an undue amount of additional experimentation.

### ***Response to Arguments***

The rejection of claims under 35 USC 112, second paragraph as being indefinite are withdrawn in view of the claim amendments.

The rejection of claims under 35 USC 101 as not having credible utility are withdrawn in view of applicants arguments. Applicants have successfully indicated that the specification disclosed enough information regarding the function of the NPY-Y7 receptor, in particular the ligand for NPY-Y7 was identified and found to be identical to the ligand for NPY-Y2. The function of NPY-Y2 was known in the prior art, therefore, one of skill in the art would readily recognize a credible utility for NPY-Y7 based on the information disclosed in the specification.

Art Unit: 1635

The rejection of claims under 35 USC 112, first paragraph (enablement), based on the lack of credible utility is withdrawn in view of withdrawal of the utility rejection. However, a new enablement rejection has been issued, based on the written description rejection.

Regarding the rejection of claims under 35 USC 112, first paragraph (written description). It is acknowledged that the claims have been amended to remove the language that indicated the polynucleotides encoded receptors that are “about” 408 amino acids in length, or “about” 405 amino acids in length. However, for the reasons set forth in the rejection above, the claims still encompass variants of the claimed sequences for which there is no written description provided in the specification. Applicants only arguments was that the claims had been amended to remove the “about” language. Applicants arguments are fully considered, but are not considered persuasive for the reasons set forth above.

#### ***Allowable Subject Matter***

12. Claim 7 is allowed because it appears to be free of the prior art and the rejections under 35 USC 101 and 112 have been overcome.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).



Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell  
March 9, 2003



**DAVE T. NGUYEN  
PRIMARY EXAMINER**